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**510(k) Summary**

**510(k) Applicant/Owner:** GRI MEDICAL & ELECTRONIC TECHNOLOGY CO., LTD.

1805 HongGao Road, XiuZhou Industry Zone,  
ZheJiang,  
China, 314031  
86-573-83916501  
86-573-83916520

**Primary Contact** Penny Northcutt

**Person for this 510(k):** REGSolutions, LLC.

717 Lakeglen Drive  
Suwanee, GA 30024  
Fax: (678) 513-0937  
Phone: (678) 428-6978

Email: pennynorthcutt@theregsolutions.com

**Summary Date:** November 17, 2011

**Device Trade Name:** GRI Sterile and Non-Sterile Surgical Drapes and Surgical Equipment Covers

**Common/Usual Name:** Surgical Drape and Drape Accessories

**Device Classification:** General & Plastic Surgery  
Class II - 21 CFR 878.4370

**Device Product Code:** KKX Surgical Drapes  
MMP Surgical Equipment Covers

**Device Description:**

GRI's single use drapes and surgical equipment covers with AAMI Liquid Barrier Level 3 claim are constructed with various base sheet fabric and reinforcement fabric types, provided in various sizes and shapes, and may contain fluid collection pouches or clear film panels as components. The base sheet fabric is a three layer laminate comprised of polypropylene.



spunbond/polypropylene meltblown/polypropylene spunbond. Layers are thermally embossed together producing a single layer with various basis weights. Fabric is typically treated to enhance water repellency and to assure static dissipation. The drape reinforcement fabrics are constructed of various configurations of spunbond, meltblown and film. The reinforcement materials are spunbond/film laminate. The primary component of these materials is polypropylene with surfactant and blue pigment.

**Predicate Device:**

GRI single use drapes and surgical equipment covers are substantially equivalent to the Kimberly Clark K083234 sterile and non-sterile surgical drapes and surgical equipment covers.

**Indications for Use:****GRI Drapes**

GRI single use drapes (both sterile and non-sterile) are made of natural or synthetic material intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

Non-sterile GRI surgical drapes are sold, in bulk as single use items, to repackager/relabeler establishments for further packaging and ethylene oxide (EtO) sterilization.

**GRI Surgical Equipment Covers**

GRI single use surgical equipment covers (both sterile and non-sterile) are protective barrier covers intended to be used to cover surgical equipment and provide a protective barrier for that equipment.

Non-sterile GRI surgical equipment covers are sold, in bulk as single use items, to repackager/relabeler establishments for further packaging and ethylene oxide (EtO) sterilization.

**Technological Characteristics and Substantial Equivalence:**

GRI single use drapes and surgical equipment covers, that is subject of this premarket notification is substantially equivalent to the predicate KC100 Surgical Drapes and Equipment Covers (K083234) in intended use statements, equivalent device construction, materials, drape design, chemical characteristics and technology performance characteristics.

The performance attributes of the GRI single use drapes and surgical equipment covers are substantially equivalent to the predicate drape.



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**Summary of Testing:**

GRI Surgical Drapes and Equipment Covers have met acceptance criteria for performance testing including biocompatibility (cytotoxicity, primary skin irritation testing and sensitization testing), hydrostatic pressure, impact penetration, tear strength, tensile strength, linting, and flammability. All tests results met acceptance criteria and were substantially equivalent to the predicate devices.

**Conclusion:**

Based on the performance testing and device attributes, it can be concluded that the GRI surgical drapes and surgical equipment covers are equivalent to the predicate devices with respect to the indications for use and technological characteristics and do not present any further safety or effectiveness questions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

GRI Medical & Electronic Technology  
C/O Ms. Penny Northcutt  
President/CEO  
REGSolutions, LLC  
717 Lakeglen Drive  
Suwanee, Georgia 30024

DEC - 1 2011

Re: K111458

Trade/Device Name: GRI Sterile and Non-sterile Surgical Drapes  
GRI Sterile and Non-sterile Surgical Equipment Covers

Regulation Number: 21 CFR 878.4370

Regulation Name: Surgical Drape and Drape Accessories

Regulatory Class: II

Product Code: KKK

Dated: November 17, 2011

Received: November 17, 2011

Dear Ms. Northcutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the \_\_\_\_\_ indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



## Indications for Use Form

### Indications for Use

510(k) Number (if known): K111458

Device Name: Surgical Drapes (Model Numbers List Attached)

### GRI Sterile and Non-sterile Surgical Drapes (various models and configurations as attached)

GRI single use drapes (both sterile and non-sterile) are made of natural or synthetic material intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

Non-sterile GRI surgical drapes are sold in bulk as single use items, to repackager/relabeler establishments for further packaging and ethylene oxide (EtO) sterilization.

The drapes are classified as level 3 per AAMI Standard PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities.

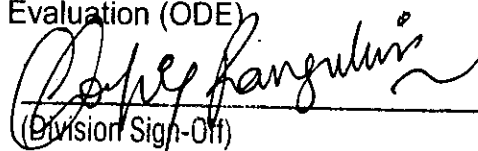
Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K111458

K111458



Surgical Drapes    Indications for Use Model Number List				
Code (Sterile)	Code (Non-Sterile)	Description	Fabric	Product Family
80-01101-S	80-01101	Femoral Angiography Drape (no window)	50gsm SMS	Angiography
80-01102-S	80-01102	Femoral Angiography Drape (single window)		
80-01103-S	80-01103	Femoral Angiography Drape (dual windows)		
80-01104-S	80-01104	Femoral Angiography Drape		
80-01105-S	80-01105	Femoral Angiography Drape (dual windows) Tri laminate material, Extra Long		
80-01106-S	80-01106	Femoral Angiography Drape (dual windows) Extra-long		
80-01107-S	80-01107	Femoral Angiography Drape (single window) with Trough		
80-01108-S	80-01108	Femoral Angiography Drape (dual windows) Tri laminate Material with Side Panel		
80-01109-S	80-01109	Femoral Angiography Drape (no window) Extra-long		
80-01110-S	80-01110	Femoral Angiography Drape (single window) Extra-long		
80-01201-S	80-01201	Femoral Angiography Drape (no window)	35gsm SMS	
80-01202-S	80-01202	Femoral Angiography Drape (single window)		
80-01203-S	80-01203	Femoral Angiography Drape (dual windows)		
80-01204-S	80-01204	Femoral Angiography Drape		
80-01205-S	80-01205	Femoral Angiography Drape (dual windows) Tri laminate material, Extra Long		
80-01206-S	80-01206	Femoral Angiography Drape (dual windows) Extra-long		
80-01207-S	80-01207	Femoral Angiography Drape (single window) with Trough		
80-01208-S	80-01208	Femoral Angiography Drape (dual windows) Tri laminate Material with Side Panel		
80-01209-S	80-01209	Femoral Angiography Drape (no window) Extra-long		
80-01210-S	80-01210	Femoral Angiography Drape (single window) Extra-long		



80-02101-S	80-02101	Bilateral Under Leg/Perineal Drape	50gsm SMS	Cardiovascular
80-02102-S	80-02102	CV Slip Drape		
80-02103-S	80-02103	Cardiovascular Incise W/Armboard cover		
80-02104-S	80-02104	Cardiovascular Universal set		
80-02105-S	80-02105	Clearview Split Drape		
80-02203-S	80-02203	Cardiovascular Incise W/Armboard cover	35gsm SMS	
80-02204-S	80-02204	Cardiovascular Universal set		
80-02205-S	80-02205	Clearview Split Drape		
80-03101-S	80-03101	Cystoscopy Drape	50gsm SMS	Cystoscopy
80-03102-S	80-03102	Cystoscopy T Drape		
80-03201-S	80-03201	Cystoscopy Drape	35gsm SMS	
80-03202-S	80-03202	Cystoscopy T Drape		
80-04101-S	80-04101	Fenestrated EENT Drape	50gsm SMS	EENT Drape
80-04104-S	80-04104	Head Drape		
80-04105-S	80-04105	Head Drape with Detachable Turban		
80-08102-S	80-08102	Eye Drape W/Fluid Pouch		
80-08103-S	80-08103	Basic ophthalmic Drape		
80-08104-S	80-08104	Ophthalmic Drape		
80-04201-S	80-04201	Fenestrated EENT Drape	35gsm SMS	
80-04204-S	80-04204	Head Drape		
80-04205-S	80-04205	Head Drape with Detachable Turban		
80-08202-S	80-08202	Eye Drape W/Fluid Pouch		
80-08203-S	80-08203	Basic ophthalmic Drape		
80-08204-S	80-08204	Ophthalmic Drape		
80-05101-S	80-05101	Side Drape 29.5x39 in	50gsm SMS	General Surgery
80-05102-S	80-05102	Bottom Drape 69x71 in		
80-05104-S	80-05104	Top Drape 59x94.5 in		
80-05107-S	80-05107	U-Drape		
80-05109-S	80-05109	Bottom drape 72x75 in double cord holders		
80-05110-S	80-05110	Top drape 50x108 in double cord holders		
80-05111-S	80-05111	Breast Chest U Drape		
80-05112-S	80-05112	Breast Drape		
80-05113-S	80-05113	Bar Drape 96x44 in w/ Arm Board Covers		
80-05114-S	80-05114	Bar Drape 106x62 in w/ Arm Board Covers		
80-05115-S	80-05115	Ortho Bar Drape		
80-05116-S	80-05116	Laparotomy Drape 100x124 in		
80-05117-S	80-05117	Laparotomy 104x120 in		
80-05118-S	80-05118	Transverse Laparotomy Drape		
80-05119-S	80-05119	Pediatric Laparotomy Drape		
80-05120-S	80-05120	Thyroid Drape		





80-05122-S	80-05122	Chest Drape	35gsm SMS		
80-05123-S	80-05123	Laparoscopic Drape			
80-05125-S	80-05125	Laparoscopic Colectomy Drape			
80-05128-S	80-05128	Side drape 38.5x77 in			
80-05129-S	80-05129	Side Drape 90x90 in			
80-05201-S	80-05201	Side Drape 29.5x39 in			
80-05202-S	80-05202	Bottom Drape 69x71 in			
80-05204-S	80-05204	Top Drape 59x94.5 in			
80-05207-S	80-05207	U-Drape			
80-05209-S	80-05209	Bottom drape 72x75 in double cord holders			
80-05210-S	80-05210	Top drape 50x108 in double cord holders			
80-05211-S	80-05211	Breast Chest U Drape			
80-05212-S	80-05212	Breast Drape			
80-05213-S	80-05213	Bar Drape 96x44 in w/ Arm Board Covers			
80-05214-S	80-05214	Bar Drape 106x62 in w/ Arm Board Covers			
80-05215-S	80-05215	Ortho Bar Drape			
80-05216-S	80-05216	Laparotomy Drape 100x124 in			
80-05217-S	80-05217	Laparotomy 104x120 in			
80-05218-S	80-05218	Transverse Laparotomy Drape			
80-05219-S	80-05219	Pediatric Laparotomy Drape			
80-05220-S	80-05220	Thyroid Drape			
80-05222-S	80-05222	Chest Drape			
80-05223-S	80-05223	Laparoscopic Drape			
80-05225-S	80-05225	Laparoscopic Colectomy Drape			
80-05228-S	80-05228	Side drape 38.5x77 in			
80-05229-S	80-05229	Side Drape 90x90 in			
80-07101-S	80-07101	C-Section Fluid Collection Drape Fenestrated Incise	50gsm SMS	Obstetrics	
80-07102-S	80-07102	C-Section Drape with Fenestrated Incise			
80-07103-S	80-07103	C-Section Drape with full Incise			
80-07104-S	80-07104	C-Section Fluid Collection Drape full Incise			
80-07201-S	80-07201	C-Section Fluid Collection Drape Fenestrated Incise	35gsm SMS		
80-07202-S	80-07202	C-Section Drape with Fenestrated Incise			
80-07203-S	80-07203	C-Section Drape with full Incise			
80-07204-S	80-07204	C-Section Fluid Collection Drape full Incise			
80-09101-S	80-09101	Lower Extremity Drape	50gsm SMS	Orthopedics	
80-09102-S	80-09102	Knee Arthroscopy Drape			



80-09104-S	80-09104	Hip Drape W/Pockets			
80-09105-S	80-09105	Body Split Drape			
80-09106-S	80-09106	Split Drape			
80-09107-S	80-09107	U-Drape			
80-09108-S	80-09108	Hand Drape			
80-09109-S	80-09109	Shoulder Arthroscopy Drape			
80-09110-S	80-09110	Shoulder Split Drape			
80-09111-S	80-09111	Beach Chair Shoulder			
80-09201-S	80-09201	Lower Extremity Drape			
80-09202-S	80-09202	Knee Arthroscopy Drape			
80-09204-S	80-09204	Hip Drape W/Pockets	35gsm SMS		
80-09205-S	80-09205	Body Split Drape			
80-09207-S	80-09207	U-Drape			
80-09208-S	80-09208	Hand Drape			
80-09209-S	80-09209	Shoulder Arthroscopy Drape			
80-09210-S	80-09210	Shoulder Split Drape			
80-11101-S	80-11101	Lithotomy Drape	50gsm SMS	Peri-GYN	
80-11102-S	80-11102	Lithotomy T-Drape			
80-11105-S	80-11105	Leggings Drape 54x31 in	35gsm SMS		
80-11201-S	80-11201	Lithotomy Drape			
80-11202-S	80-11202	Lithotomy T-Drape			
80-11205-S	80-11205	Leggings Drape 54x31 in			
80-12101-S	80-12101	Half Drape	50gsm SMS	Ancillary	
80-12102-S	80-12102	Medium Drape			
80-12103-S	80-12103	Large Drape			
80-12104-S	80-12104	XL Drape	35gsm SMS		
80-12201-S	80-12201	Half Drape			
80-12202-S	80-12202	Medium Drape			
80-12203-S	80-12203	Large Drape			
80-12204-S	80-12204	XL Drape			
85-07341-S	85-07341	7" with pull tab Stockinette Drape	Polyester knit stockinette	Stockinette Drape	
85-09481-S	85-09481	9" with pull tab Stockinette Drape			
85-12481-S	85-12481	12" with pull tab Stockinette Drape			
85-16481-S	85-16481	16" with pull tab Stockinette Drape			
85-07340-S	85-07340	7" without pull tab Stockinette Drape			
85-09480-S	85-09480	9" without pull tab Stockinette Drape			
85-12480-S	85-12480	12" without pull tab Stockinette Drape			
85-16480-S	85-16480	16" without pull tab Stockinette Drape			

### Key for Surgical Drape Codes:

Prefix                      80=Surgical drape series  
 Suffix – 1&2              First two positions represent product category  
                                     01 - Angiography  
                                     02 - Cardiovascular  
                                     03 - Cystoscopy  
                                     04 - EENT



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	05 - General Surgery
	07 - Obstetrics
	09 - Orthopedic
	11 - Peri-GYN
	12 - Ancillary
	14 - Accessories
Suffix - 3	Third position represents "fabric"
	1 = SMS - 50gsm
	2 = SMS - 35gsm
Suffix - 4&5	Fourth and Fifth positions represent Product identification in sequential order of development
Suffix - 6	Sixth position represents "packaging"
	S = Sterile



## Indications for Use Form

### Indications for Use

510(k) Number (if known): K111458

Device Name: Surgical Equipment Covers (Model Numbers List Attached)

### **GRI Sterile and Non-sterile Surgical Equipment Covers (various models and configurations as attached)**

GRI single use surgical equipment covers (both sterile and non-sterile) are protective barrier covers intended to be used to cover surgical equipment and provide a protective barrier for that equipment.

Non-sterile GRI surgical equipment covers are sold in bulk as single use items, to repackager/ relabeler establishments for further packaging and ethylene oxide (EtO) sterilization.

The covers are classified as level 3 per AAMI Standard PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K111458



Surgical Equipment Covers		Indications for Use Model Number List		
80-13101-S	80-13101	Back Table Cover 44x75in	43gsm SMS	Back Table Covers
80-13102-S	80-13102	Back Table Cover 44x90in		
80-13103-S	80-13103	Back Table Cover 50x90in		
80-13104-S	80-13104	Back Table Cover 80x90in		
80-13107-S	80-13107	Back Table Cover 55x75in		
80-13108-S	80-13108	Back Table Cover 60x75in		
80-13109-S	80-13109	Back Table Cover 60x90in		
80-13110-S	80-13110	Back Table Cover 44x44in		
80-13105-S	80-13105	Mayo Stand Cover 23x54in	43gsm SMS	Mayo Stand Covers
80-13106-S	80-13106	Mayo Stand Cover 29.5x57in		
80-14101-S	80-14101	Underbuttocks Drape w/Pouch	50gsm SMS	Accessories
80-14102-S	80-14102	Underbuttocks Drape 48x36in		
80-14103-S	80-14103	Drape Underbuttocks W/Pouch		
80-14104-S	80-14104	Underbuttocks Drape 38x44in		

#### Key for Surgical Drape Codes:

- Prefix                      80=Surgical drape series
- Suffix – 1&2              First two positions represent product category
- 01 - Angiography
  - 02 - Cardiovascular
  - 03 - Cystoscopy
  - 04 - EENT
  - 05 - General Surgery
  - 07 - Obstetrics
  - 09 - Orthopedic
  - 11 - Peri-GYN
  - 12 - Ancillary
  - 14 - Accessories
- Suffix - 3                      Third position represents "fabric"
- 1 = SMS - 50gsm
  - 2 = SMS - 35gsm
- Suffix – 4&5                      Fourth and Fifth positions represent Product identification in sequential order of development
- Suffix – 6                      Sixth position represents "packaging"
- S = Sterile